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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,579	11/14/2006	Xin Jiang	039386-2266	4467

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EXAMINER
MONSHIPOURI, MARYAM

ART UNIT	PAPER NUMBER
1656	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/534,579	JIANG ET AL.	
	Examiner	Art Unit	
	Maryam Monshipouri	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *98-119* is/are pending in the application.

4a) Of the above claim(s) *100, 104, 107-117, 119* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *98,101-103,105,106 and 118* is/are rejected.

7)☒ Claim(s) *99* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicant's response to restriction requirement filed 9/1/2007 is acknowledged. Applicant elected Group I (claims 98-99, 101-103, 105 and 118, SEQ ID NO:6 only) without traverse. Claims 100, 104, 106-117, 119 are withdrawn as drawn to non-elected invention.

Claim Objections

Claims 98-99, 101-103, 105, 118 are objected to because of the following informalities: said claims still recite non-elected subject matter, namely SEQ ID NO:8. Applicant is advised to delete non-elected subject matter from said claims. Appropriate correction is required.

Priority

It is noted that no priority data is provided at the first page of the specification. Applicant is advised to provide said data in response to this office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 98-99, 101-103, 105-106 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "biologically active fragment" in claim 98 (and its dependent claims 99, 102, 103, 105-106) is unclear. In page 30 of the disclosure applicant has defined "biologically active" as a protein having structural, regulatory or biochemical functions of a naturally occurring molecule. It is indefinite as to what is a structural function and what are the exact functions (regulatory or biochemical) of claimed fragment. Appropriate clarification is required.

Claims 103, 106, and 118 and are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "portion In claim 103 (and its dependent claim 104) and claim 118 is unclear. It is unknown how many bases constitute a "portion".

Claims 98, 101-103, 105-106, 118 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for isolated polypeptides comprising SEQ ID NO:6 or isolated polynucleotides/RNA comprising SEQ ID NO:27, does not reasonably provide enablement for

any of the following with no specific function: (a) "biologically active" and/or immunogenic fragments of SEQ ID NO:6 (see claims 98, 101-102, 105), (b) isolated polynucleotides encoding said fragments, (c) isolated DNA/mRNA displaying 90% identity to SEQ ID NO:27 and (d) isolated DNA/mRNA comprising a "portion" of SEQ ID NO:27 (see claims 103, 106 and 118) that specifically identifies said DNA sequence.

The criteria for undue experimentation, summarized in *re Wands*, 8, USPQ2n 1400 (Fed. Cir. 1988) are: 1) the quantity of experimentation necessary, 2) the amount of direction or guidance presented, 3) the presence and absence of working examples, 4) the nature of the invention, 5) the state of prior art, 6) the relative skill of those in the art, 7) the predictability or unpredictability of the art, and 8) the breadth of the claims.

The disclosure fails to teach which residues within SEQ ID NO:6 must be retained in its "biologically active" or "immunogenic" fragments such that they retain lipoprotein cholesterol ester transferase activity. This information is also lacking with respect to critical residues in SEQ ID NO:27 that assign function to the expression products of polynucleotides claimed in claims 103(ii-v), and 118 (ii-v). No examples of such amino acid or nucleotide residues are provided. Current state of prior art indicates that

once many residues of a full length polypeptide or its encoding sequence is simultaneously deleted, substituted, etc. said variant product is no longer capable of retaining the function associated with said full-length polypeptide or its encoding DNA/mRNA sequence.

Therefore due to lack of sufficient guidance and examples provided and due to unpredictability of prior art as to which residues in SEQ ID NO:6 or SEQ ID NO:27 are in charge of assigning function thereto one of skill in the art has to go though the burden of undue experimentation in order to screen for those amino acid fragments or DNA/RNA homologs, oligonulceotide etc. which are supported by this application and as such the claims go beyond the scope of the disclosure.

Since the polyhnucoleotides of Claim 103 are not fully enabled the expression products of said polynucleotides (i.e. claim 106). is not fully enabled either.

Claims 98, 101-103, 105-106, 118 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed,

had possession of the claimed invention. Claims 98, 101-103, and claim 118 are directed to a **genera** of polypeptide fragments, DNA fragments or DNA homologs that are not adequately described in the specification.

The disclosure does not contain any disclosure of the function of all polypeptide fragments or DNA/RNA sequences that are recited in claim 103 (ii-v) and claim 118 (ii-v), also see sections (a)-(d) above. The genera of polypeptide fragments and DNA/RNA fragments that comprise these above molecules are large variable genera with the potentiality of retaining (in the case of polypeptides) or encoding many different proteins (in the case of DNA/mRNA sequences). Therefore, many functionally unrelated DNAs and polypeptide fragments are encompassed within the scope of these claims, including partial DNA sequences. The specification discloses only a **single species** of each claimed genus (namely SEQ ID NO:6, and SEQ ID NO:27) which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised interim guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 98, 101-102, 103, 105-106 and 118 are rejected under 35 U.S.C. 102(b) as being anticipated by Drayna et al. (Nature, 1987, 327, 632-634). Drayna teaches a recombinant lipid associated molecule having an amino acid sequence displaying 97.4% identity to SEQ ID NO:6 of this invention (see the attached sequence alignment), which can be considered to be both a biologically active and an immunogenic fragment of SEQ ID NO:6 anticipating claims 98, 101-102, 105. Said amino acid sequence of Drayna is encoded by a DNA sequence displaying 96.8% identity to SEQ

ID NO:27 of this invention, anticipating claims 103 and 118. Drayna also teaches recombinant expression of its DNA sequence, anticipating claim 106.

Allowable Subject Matter

Claim 99 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. This is because SEQ ID NO:6 and its encoding DNA sequence are free of prior art. Further, the prior art does not teach or suggest preparing such specifically claimed sequences. Hence said sequences are both novel and non-obvious.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maryam Monshipouri whose telephone number is (571) 272-0932. The examiner can normally be reached on Tues.-Fri., from 7:00 a.m to 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleene Kerr Bragdon can be reached on (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

M. Monshi
Maryam Monshipouri Ph.D.

Primary Examiner